

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

IAN WALLACE,)
)
Plaintiff,)
)
vs.) **No. 4:18-cv-01859 PLC**
)
PHARMA MEDICA RESEARCH, INC.;)
TRIS PHARMA, INC.; ROXANE)
LABORATORIES, INC.; HIKMA)
LABS, INC.; and WEST-WARD)
COLUMBUS, INC.)
)
Defendants.)

SECOND AMENDED COMPLAINT

COMES NOW the Plaintiff, Ian Wallace, by and through his undersigned counsel, and for his cause of action against Defendants, states as follows:

PARTIES, JURISDICTION & VENUE

1. That the petitioner is a resident and citizen of Madison County, Illinois.
2. That Pharma Medica Research, Inc. (hereinafter “PMR”) is a Canadian corporation headquartered and with its principal place of business in Mississauga, Ontario, Canada. PMR maintains a registered agent located at 1 North Brentwood Blvd., 10th Floor, St. Louis, Missouri. Further, PMR at all times relevant hereto operated a “Screening Clinic” and “Phase I Clinic” at 400 Fountain Lakes Boulevard, St. Charles, Missouri.
3. That Tris Pharma, Inc. (hereinafter “TPI”), is a New Jersey corporation with its principal place of business in New Jersey. TPI sponsored as master and PMR as agent a certain study at PMR’s St. Charles, Missouri, facility as referenced in documents labeled PMRI 00168 through 00223. Plaintiff was a participant in that study.



4. Roxane Laboratories, Inc. (hereinafter “RLI”), is an Ohio corporation with its principal place of business in Ohio. RLI sponsored as master and PMR as agent a certain study at PMR’s St. Charles, Missouri, facility as referenced in documents bates labeled PMRI 00352 through 00391. Plaintiff was a participant in that study. RLI has been succeeded by West-Ward Columbus, Inc. (hereinafter “WCI”), and/or by Hikma Labs, Inc. (hereinafter “HLI”). WCI is a Delaware corporation with its principal place of business in London, England. HLI is a Nevada corporation with its principal place of business in London, England.

5. This action is of civil nature and the amount in controversy, excluding interest and costs, exceeds the sum specified by 28 U.S.C § 1332. Every issue of law and fact is wholly between citizens of different states. Consequently, jurisdiction of this Court is proper.

6. Venue is proper under 28 U.S.C. § 1391(b)(2)-(d) because Defendant is subject to personal jurisdiction of this Court, having research facilities, businesses, and/or office locations in Missouri, including St. Louis and St. Charles, Missouri.

COUNT I
(Negligence – *Wallace v. PMR*)

7. Plaintiff, on or about March 23, 2016, through April 23, 2016, and again on or about June 10, 2016, through June 14, 2016, Plaintiff participated in a research studies at PMR’s facility located in St. Charles, Missouri. During this study plaintiff was repeatedly required to submit blood samples for testing, with such samples drawn by Defendant’s unknown employees and/or contractors, acting within the course and scope of their employment or agency relationship with the PMR. At this point, the identities of those employees are unknown but will be obtained in discovery.

8. That based on the above, PMR owed a duty to Plaintiff and others similarly situated to draw blood samples in a safe and sanitary fashion with properly trained, qualified, and supervised

staff.

9. That in violation of the aforesaid duty Defendant committed one or more of the following negligent acts and/or omissions:

- (a) Failed to properly train its employees and/or agents to perform blood extractions in a safe and sanitary fashion;
- (b) Failed to properly screen its employees and/or agents to ascertain whether said employees and/or agents were qualified and properly trained to draw blood samples in a safe and sanitary fashion;
- (c) Failed to properly supervise its employees and/or agents to insure that those employees and/or agents drew blood in a safe and sanitary fashion;
- (d) Failed to supply sufficient equipment to allow for the safe and sanitary drawing of blood samples;
- (e) Failed to properly clean and sterilize equipment used to draw blood samples;
- (f) Failed to properly screen its employees, agents, and/or other participants in the study to determine whether such individuals were infected with contagious diseases; and
- (g) Failed to properly dispose of unsanitary equipment used in the blood drawing process.

10. That as a direct and proximate result of the aforesaid, Plaintiff contracted Hepatitis C during the blood drawing process.

11. That as a further and proximate result of the aforesaid, Plaintiff has experienced and will continue to experience great pain and mental anguish. Plaintiff has incurred and will continue to incur medical bills to obtain treatment for his injuries. Plaintiff has lost income and will likely lose income in the future. Plaintiff's condition is such that it will require convalescent care in the future. Plaintiff has sustained loss of normal life.

WHEREFORE, Plaintiff prays for a judgment against Defendant for an amount in excess of \$75,000.00 and for costs of this action.

COUNT II

(Negligence – Wallace vs. TPI)

NOW COMES the plaintiff, Ian Wallace, by and through his undersigned counsel, and for his cause of action against TPI, states as follows:

1-11. Plaintiff repeats, realleges, and incorporates herein by reference paragraphs 1-11 above.

12. That TPI sponsored study number 2015-3952 pursuant to which it employed PMR to test on humans certain medications designed, manufactured, supplied, and created by TPI. TPI controlled the actions of PMR or had the right to control the actions of PMR in said study. Such control enabled TPI to visit PMR's facility to assure compliance with TPI's instructions, policies, rules, protocols, and guidelines; monitor PMR's conduct; request all information from PMR during the study; require reports from PMR; require audits; require quality assurance and quality control systems; require specific testing procedures including blood draws; regulate meal and sleep times of study participants; and all other restrictions set forth in the aforesaid study guidelines. Defendant also required PMR carry insurance for the study participants.

13. That at all relevant times, PMR was acting as the agent for TPI in the scope of its employment by TPI for the aforesaid study. As such, TPI is responsible for PMR's actions during the study.

14. That Plaintiff sustained the damages described in Count I during the study at issue. Plaintiff's damages are aggravated by PMR's assertion that it did not carry insurance which TPI was to require PMR carry for Plaintiff and others in the study.

WHEREFORE, Plaintiff prays for a judgment against Defendant for an amount in excess of \$75,000.00 and for costs of this action.

COUNT III

(Negligence – Wallace vs. RLI, WCI and HLI)

NOW COMES the plaintiff, Ian Wallace, by and through his undersigned counsel, and for his cause of action against RLI, WCI, and HLI, states as follows:

1-11. Plaintiff repeats, realleges, and incorporates herein by reference paragraphs 1-11 above.

12. That RLI sponsored study number DESV-T25-PVFS-1 pursuant to which it employed PMR to test on humans a certain medication designed, manufactured, supplied, and created by RLI. RLI controlled the actions of PMR or had the right to control the actions of PMR in said study. Such control enabled RLI to visit PMR's facility to assure compliance with RLI's instructions, policies, rules, protocols, and guidelines; monitor PMR's conduct; request all information from PMR during the study; require reports from PMR; require audits; require quality assurance and quality control systems; require specific testing procedures including blood draws; regulate meal and sleep times of study participants; and all other restrictions set forth in the aforesaid study guidelines. Defendant also required PMR carry insurance for the study participants.

13. That at all relevant times, PMR was acting as the agent for RLI in the scope of its employment by RLI for the aforesaid study. As such, RLI is responsible for PMR's actions during the study.

14. That Plaintiff sustained the damages described in Count I during the study at issue. Plaintiff's damages are aggravated by PMR's assertion that it did not carry insurance which RLI was to require PMR carry for Plaintiff and others in the study.

WHEREFORE, Plaintiff prays for a judgment against Defendant for an amount in excess of \$75,000.00 and for costs of this action.

COUNT IV
(*Res Ispa Loquitur – Wallace v. PMR*)

1. On or about March 23, 2016, through April 23, 2016, and again on or about June 10, 2016, through June 14, 2016, Plaintiff participated in research studies at PMR's facility located in St. Charles, Missouri. During this study Plaintiff was repeatedly required to submit blood samples for testing, with such samples drawn by Defendant's unknown employees and/or contractors, acting within the course and scope of their employment or agency relationship with PMR. The blood samples were extracted from Plaintiff on some occasions while he was asleep. At this point, the identities of those employees are unknown but will be obtained in discovery.

2. That based on the above, PMR owed a duty to Plaintiff and others similarly situated to draw blood samples in a safe and sanitary fashion with properly trained, qualified, and supervised staff.

3. That in violation of the aforesaid duty, Defendant committed one or more of the following negligent acts and/or omissions:

- (a) Failed to properly train its employees and/or agents to perform blood extractions in a safe and sanitary fashion;
- (b) Failed to properly screen its employees and/or agents to ascertain whether said employees and/or agents were qualified and properly trained to draw blood samples in a safe and sanitary fashion;
- (c) Failed to properly supervise its employees and/or agents to insure that those employees and/or agents drew blood in a safe and sanitary fashion;
- (d) Failed to supply sufficient equipment to allow for the safe and sanitary drawing of blood samples;

- (e) Failed to properly clean and sterilize equipment used to draw blood samples;
- (f) Failed to properly screen its employees, and/or agents, and/or other participants in the study to determine whether such individuals were infected with contagious diseases;
- (g) Failed to properly dispose of unsanitary equipment used in the blood drawing process.

4. That as a direct and proximate result of the aforesaid, Plaintiff contracted Hepatitis C during the blood drawing process.

5. That as a further and proximate result of the aforesaid, Plaintiff has experienced and will continue to experience great pain and mental anguish. Plaintiff has incurred and will continue to incur medical bills to obtain treatment for his injuries. Plaintiff has lost income and will likely lose income in the future. Plaintiff's condition is such that it will require convalescent care in the future. Plaintiff has sustained loss of normal life.

6. That the infection with the Hepatitis C virus from blood draws does not ordinarily happen in the absence of negligence by those who draw blood and/or those who supervise/monitor the blood draws.

7. That the instrumentalities and persons who drew blood from Plaintiff which caused Plaintiff's injury were at all relevant times under the care and management of PMR.

8. That PMR possess either superior knowledge of or means of obtaining information about the cause of the infection.

WHEREFORE, Plaintiff prays for a judgment against Defendant for an amount in excess of \$75,000.00 and for costs of this action.

COUNT V

(Res Ispa Loquitur – Wallace vs. TPI)

NOW COMES the plaintiff, Ian Wallace, by and through his undersigned counsel, and for his cause of action against TPI, states as follows:

1-8. Plaintiff repeats, realleges, and incorporates herein by reference paragraphs 1-8 above.

9. That TPI sponsored study number 2015-3952 pursuant to which it employed PMR to test on humans certain medications designed, manufactured, supplied, and created by TPI. TPI controlled the actions of PMR or had the right to control the actions of PMR in said study. Such control enabled TPI to visit PMR's facility to assure compliance with TPI's instructions, policies, rules, protocols, and guidelines; monitor PMR's conduct; request all information from PMR during the study; require reports from PMR; require audits; require quality assurance and quality control systems; require specific testing procedures including blood draws; regulate meal and sleep times of study participants; and all other restrictions set forth in the aforesaid study guidelines. Defendant also required PMR carry insurance for the study participants.

10. That at all relevant times, PMR was acting as the agent for TPI in the scope of its employment by TPI for the aforesaid study. As such, TPI is responsible for PMR's actions during the study.

11. That Plaintiff sustained the damages described in Count I during the study at issue. Plaintiff's damages are aggravated by PMR's assertion that it did not carry insurance which TPI was to require PMR carry for Plaintiff and others in the study.

WHEREFORE, Plaintiff prays for a judgment against Defendant for an amount in excess of \$75,000.00 and for costs of this action.

COUNT VI

(Res Ispa Loquitur – Wallace vs. RLI, WCI and HLI)

NOW COMES the plaintiff, Ian Wallace, by and through his undersigned counsel, and for his cause of action against RLI, WCI, and HLI, states as follows:

1-8. Plaintiff repeats, realleges, and incorporates herein by reference paragraphs 1-11 above.

9. That RLI sponsored study number DESV-T25-PVFS-1 pursuant to which it employed PMR to test on humans a certain medication designed, manufactured, supplied, and created by RLI. RLI controlled the actions of PMR or had the right to control the actions of PMR in said study. Such control enabled RLI to visit PMR's facility to assure compliance with RLI's instructions, policies, rules, protocols, and guidelines; monitor PMR's conduct; request all information from PMR during the study; require reports from PMR; require audits; require quality assurance and quality control systems; require specific testing procedures including blood draws; regulate meal and sleep times of study participants; and all other restrictions set forth in the aforesaid study guidelines. Defendant also required PMR carry insurance for the study participants.

10. That at all relevant times, PMR was acting as the agent for RLI in the scope of its employment by RLI for the aforesaid study. As such, RLI is responsible for PMR's actions during the study.

11. That Plaintiff sustained the damages described in Count I during the study at issue. Plaintiff's damages are aggravated by PMR's assertion that it did not carry insurance which RLI was to require PMR carry for Plaintiff and others in the study.

WHEREFORE, Plaintiff prays for a judgment against the defendant for an amount in excess of \$75,000.00 and for costs of this action.

PLAINTIFF PRAYS FOR TRIAL BY JURY

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing was transmitted via electronic mail this 12th day of December 2019, to the following:

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